510(k) Summary per 21 CFR 807.92

510(k) # K120398

AUG 16 2012

510(k) SUBMITTER:	Hollywog, LLC 2830 Amnicola Highway Chattanooga, TN 37406
ESTABLISHMENT REGISTRATION:	3008585473
CONTACT:	Michael W. Treas, Chief Compliance Officer
DATE PREPARED:	August 15, 2012
PROPRIETARY NAME:	WiTouch™ Pro
PANEL:	Neurology
REGULATION NUMBER:	CFR Title 21, 882.5890
CLASSIFICATION:	Class II
PRODUCT CODES:	GZJ (Stimulator, Nerve, Transcutaneous, For Pain Relief); NYN (Stimulator, Electrical, Transcutaneous, For Arthritis)
COMMON NAME:	Transcutaneous electrical nerve stimulator for pain relief.

Description:

The WiTouch™ Pro medical device is a Transcutaneous Electrical Nerve Stimulator (TENS) used to reduce the perception of pain by electrically stimulating peripheral nerves across the skin (transcutaneously). The design consists of a battery powered current generator with integral electrodes and replaceable electrical dispersive hydrogel pads (gel-pads). One side of the adhesive gel-pad adhere to the integral electrode, and the other side adhere the device to the healthy intact skin of the patient's back to provide a transcutaneous analgesic electrical stimulus to the painful area.

Indications for Use:

The WiTouch™ Pro Transcutaneous Electrical Nerve Stimulator Device is used for the symptomatic relief and management of chronic intractable back pain and relief of pain of the upper and lower back associated with arthritis. It is also used for adjunctive treatment for post-surgical and post-trauma acute back pain.

Intended Use:

The intended use is to provide analgesic electrical stimulus to reduce the perception of back pain by electrically stimulating peripheral nerves across the skin (transcutaneously).

Accessories:

The device utilizes hydrogel pads (gel-pads) for achieving the indications for use and intended use. The composition of the gel-pads is common materials found in the electrode industry. The uniqueness of the gel-pads is in the shape. The maximum average power density of the electrodes with the gel-pads applied is less than 0.25 watts per square centimeter of electrode conductive surface area to reduce the risk of thermal burns which is consistent with the referenced predicate devices.

Substantially Equivalent Predicate Devices

510(k) #	*Predicate Proprietary Trade Name*	*Predicate Regulation, Classification, and Product Code(s)*
K061650	Empi SELECT®	CFR Title 21, Sec. 882.5890, Class II, GZJ, NYN
K061516	Staodyn® Max Preset TENS	CFR Title 21, Sec. 882.5890, Class II, GZJ, NYN

The predicate devices utilize flexible wires between the electrodes and the electrical stimulus generator; thus, increases the indications for use to the lower back and to body surfaces with greater ranges of motion (e.g., knee, shoulder, elbow, and hip).

The intended design of the WiTouch™ Pro device limits the application for use to the anatomical sites of the upper and lower back. The design includes carbon rubber electrodes that are intended for reuse and are permanently-affixed to a rigid surface of the electrical stimulus generator. The unique connection makes the electrodes integral to the generator. The connection and shape of the electrodes limit application of the device to the contours of the back. These unique characteristics of the integral electrodes are insignificant as it relates to safety and effectiveness, and is not critical to the intended use between the device and the referenced predicate devices.

The referenced predicate devices utilize affixed buttons as the sole method to control the electrical stimulus generator on/off and intensity up/down. The WiTouch™ Pro utilizes an additional method of a wireless remote control radio frequency transceiver to control the electrical stimulus generator on/off and intensity up/down. The transceiver operates in the ISM radio frequency band for wireless medical technology. This uniqueness of controlling the electrical stimulus generator by utilizing a radio frequency transceiver is insignificant as it relates to safety and effectiveness, and is not critical to the intended use between the device and the referenced predicate devices

The characteristics of the analgesic electrical stimulus output between the device and the referenced predicate devices are substantially equivalent as it relates to safety and effectiveness.

510(k) Summary per 21 CFR 807.92

510(k) # K120398

Technological characteristics and physical properties of the WiTouch Pro device and the referenced predicate devices:

510(k) Number		K120398	K061650	K061516
Device Name and Model		WiTouch™ Pro	Empi® Select	Staodyn® Max preset TENS
Manufacturer		Hollywog	EMPI	Compex Technologies
TENS Device Power Source (DC battery)		Battery 1.5VDC (2-Alkaline AAA)	Battery 1.5VDC (3-Alkaline AAA)	Battery 1.5VDC (3-Alkaline AAA)
Number of Output Modes		4	4	4
Number of Output Channels:	Synchronous or Asynchronous?	1 Channel Asynchronous	2 Channels Asynchronous	2 Channels Synchronous
Software/Firmware/Microprocessor Control?		Yes	Yes	Yes
Automatic Shut Off?		Yes	Yes	Yes
User Override Control?		Yes	Yes	Yes
Indicator Display:	On/Off Status?	Yes	Yes	Yes
	Low Battery?	Yes	Yes	No
	Voltage/Current Level?	No	No	No
Timer Range (minutes)		30	1 to 30	1 to 30
Weight (lbs., oz.)		4.8 oz. w/ batteries included	4.9 oz. w/ batteries included	5.15 oz. w/ batteries included
Dimensions (in.) [W x H x D]		7.5"(W) x 3.5(H)" x 0.7"(D)	2.38"(W) x 1.38"(H) x 4.31"(D)	2.5"(W) x 5.25"(H) x 1.0"(D)
Housing Material and Construction		Silicone & ABS	Plastic	Plastic
Waveform (e.g., pulsed monophasic, biphasic)		Pulsed biphasic	Pulsed biphasic	Pulsed biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)		Square	Square	Square
For multiphasic waveforms only:	Symmetrical phases?	No	No	Yes
	Step-1 and Step-3 Phase Duration (include units), (state range, if applicable), (both phases, if asymmetrical)	120µs	0 to 400µs at 50% peak amplitude	0 to 300µs
	Step-2 Phase Duration (include units), (state range, if applicable), (both phases, if asymmetrical)	480µs	0 to 400µs at 50% peak amplitude	0 to 300µs
Maximum Current Density, (mA/cm², r.m.s.)		0.12mA@500 Ω	<10mA @500 Ω	<10mA @500 Ω
Maximum Average Current (average absolute value), mA		1.6mA@500 Ω	<10mA @500 Ω	<10mA @500 Ω
Maximum Average Power Density, (W/cm²), (using smallest electrode conductive surface area)		0.00069W/cm2@ 500 Ω	<0.25 W/cm2 at 500 Ω	<0.25 W/cm2 at 500 Ω

Declarations of Conformity
The device complies with the following FDA recognized standards:

FDA Recognized Number 5-4, IEC 60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 1988 Amendment 1, 1991-11, Amendment 2, 1995. (General)

FDA Recognized Number 5-60, IEC 60601-1-2 Int. 1 Third Edition/I-SH 01:2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests, Interpretation Sheet. (General)

FDA Recognized Number 5-41, Medical electrical equipment – Part 1-4: General requirements for safety- Collateral standard: Programmable electrical medical systems, edition 1.1. (General)

FDA Recognized Number 17-5, IEC 60601-2-10 1987/Amendment 1 2001, Medical electrical equipment – Part 2-10: Particular requirements for the safety of nerve and muscle stimulators. (Neurology)

FDA Recognition Number 2-156: AAMI/AMSI/ ISO 10993-1:2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. (Biocompatibility)

FDA Recognition Number 2-153 (Electrodes) ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity. (Biocompatibility)

FDA Recognized Standard 2-173 (Electrodes) Recognition Number 2-173: AAMI / ANSI / ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization. (Biocompatibility)

Truthful and Accurate Statement
A statement was included in the Premarket Notification attesting to the truthfulness and accuracy of the information provided.

Further Information
In the event that additional information is required, please contact:

Michael W. Treas
Chief Compliance Officer
Hollywog, LLC
2830 Amnicola Highway
Chattanooga, TN 37406

Telephone: (423) 305-7778 ext. 108
Fax: (423) 305-7867
E-mail: mike.treas@hollywog.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 16 2012

Hollywog, LLC
Mr. Michael Treas
Chief Compliance Officer
2830 Amnicola Highway
Chattanooga, TN 37406

Re: K120398
Trade/Device Name: WiTouch Pro
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous nerve stimulator, for pain relief
Regulatory Class: II
Product Code: GZJ, NYN
Dated: July 10, 2012
Received: July 12, 2012

Dear Mr. Treas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **K120398**

Device Trade Name: **WiTouch® Pro**

Indications for Use:

The WiTouch® Pro Transcutaneous Electrical Nerve Stimulator Device is used for the symptomatic relief and management of chronic intractable back pain and relief of pain of the upper and lower back associated with arthritis. It is also used for adjunctive treatment for post-surgical and post-trauma acute back pain.

Prescription Use √ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K120398